UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

**OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES**

MEMORANDUM

DATE: September 1, 2006

SUBJECT: Section 3 Registration of Canadian Wilderness Oil (EPA Reg. #: 82016-E), Containing 10% Fir Needle Oil (Active Ingredient) and Fresh Cab (EPA Reg. #: 82016-R), Containing 2% Fir Needle Oil (Active Ingredient). Review of Product Chemistry, Acute Toxicity and Product Performance.

DP No.:	330499 & 330733	Decision No.:	365844 & 365258
PC Code:	129035	MRID Nos.:	467844-01 – 467844-16
EPA Reg. No.:	82016-E & 82016-R		
Chemical Class:	Biopesticide		

From: Manying Xue, Chemist
BPB/BPPD (7511P)

Through: Russell S. Jones, Ph.D., Senior Biologist
BPB/BPPD (7511P)

To: Linda Hollis, Chief
BPB/BPPD (7511P)

Action Requested:

EARTH-KIND, Inc. DBA Crane Creek Gardens has submitted a petition for the registration of Canadian Wilderness Oil and Fresh Cab, containing fir needle oil (the active ingredient) of 10% and 2%, respectively. Canadian Wilderness Oil is the manufacturing use product (MP); and Fresh Cab is the end use product (EP). Fresh Cab has been classified as a biochemical which is proposed to be used to control rodents in enclosed areas such as tractor cabs, electrical boxes, cabin cruisers, RV homes, and in non-living areas such attics, cellars, storage areas, garages, etc.

In support of this petition, the petitioner has submitted product chemistry studies of Canadian Wilderness Oil at nominal concentration of 10% of the active ingredient, fir

needle oil and the end use product Fresh Cab at nominal concentration of 2.0% of the active ingredient, fir needle oil (MRIDs 46784401 and 46784414), basic Confidential Statements of Formula (CSFs, dated 12/10/2005), proposed labels, acute toxicity studies for Canadian fir needle (unregistered technical, MRIDs: 467844-02 through 464349-07) and Canadian Wilderness Oil (MP, MRIDs: 467844-08 through 464349-13), product performance study for the end use product, fresh cab (MRID 467844-16), and waiver requests (MRID 46784415) for acute oral toxicity (OPPTS 870.1100) acute dermal toxicity (OPPTS 870.1200) acute inhalation toxicity (OPPTS 870.1300) primary eye irritation (OPPTS 870.2400) primary dermal irritation (OPPTS 870.2500) dermal sensitization (OPPTS 870.2600) for the end use product, fresh cab.

BPPD has reviewed and evaluated the submissions for Fir needle oil, Canadian Wilderness Oil and Fresh Cab. The decisions are made to reflect the current OPP policies.

Regulatory Recommendations:

BPPD has examined the submitted product chemistry data for Canadian Wilderness Oil, the manufacturing use product and Fresh Cab, the end use product, proposed label, CSFs, acute toxicology studies for the Canadian fir needle and Canadian Wilderness Oil, product performance study and waiver requests for the end use product, fresh cab. BPPD concludes that pending resolution of the **deficiencies** noted below:

Directions for Use (OPPTS 860.1200)

1. The submitted label for Canadian wilderness oil (EPA Reg. No. 82016-E), the manufacturing use product, is not acceptable. The petitioner needs to submit a revised label with the standard of label format. The descriptions of directions for use, hotline number, hazards to humans and domestic animals, and personal protective equipment (PPE), etc have been provided in the label.

2. The submitted label for the end-use product (Fresh Cab, EPA Reg. No. 82016-R), a rodent repelling biopesticide, is not acceptable. The petitioner needs to submit a revised label with the standard of label format. The descriptions of environmental hazards to humans and domestic animals, personal protective equipment (PPE), and hotline number, etc. have been provided.

Product Properties (OPPTS 830 Series)

3. The submitted product chemistry study for Fresh Cab is not adequate to satisfy the OPPTS guidelines 830 Series. The registrant needs to 1) consistently list the percentage of the a.i. on the CSF (2.0%) and label (2%); 2) provide a MSDS of the TGAI/MP Canadian wilderness Oil from the supplier listed on the CSF and remove any others; 3) provide the methods for physical/chemical properties; and 4) data are provided for oxidation/reduction (chemical incompatibility) and explodability.

Inert ingredient information may be entitled to confidential treatment

4. The submitted product chemistry study for Canadian wilderness oil is unacceptable. The classification of the product chemistry study can be upgradeable if 1) the CAS No. for [redacted] is corrected on the CSFs; 2) the names for [redacted] are corrected on the CSFs; 3) the purposes of the inert ingredients in the formulations and their suppliers are specified on the CSFs; 4) MSDSs for the inert ingredients are provided by the suppliers listed in MRID 46784401; 5) descriptions of the process conditions and equipment and product packaging are submitted; 6) methods are provided for the relevant physical and chemical characteristics; 7) data are provided for chemical incompatibility, explodability, storage stability and corrosion characteristics; and 8) PC codes are needed to be assigned for [redacted]

5. The petitioner must submit product chemistry study for fir needle oil (TGAI) based on OPPTS Guidelines 830 Series to meet product chemistry data requirement for the Section 3 registration as specified under 40CFR 158.690(a).

Immunotoxicity, 90-Day Dermal Toxicity & 90-Day Inhalation Toxicity (OPPTS 870.7800, 870.3250 & 870.3465)

6. No studies of immunotoxicity, 90-day dermal toxicity & 90-day inhalation toxicity for Canadian Wilderness Oil, the manufacturing use product or Fresh Cab, the end use product or waiver request for these studies have been submitted with this petition. The petitioner needs to submit these studies or a strong justification for a waiver request.

Product Performance (OPPTS 810.1000)

7. Based on the test results, it can not be concluded that mice are being repelled by this product. The means for control treatment tanks must be reported with their associated standard errors. The data must be statistically analyzed for mean comparison of two treatment means and determination of statistically significant differences between the two groups (treated and untreated/control). Obviously, caching food is not the best way to measure preference between control and treated samples, therefore no conclusion should be made from these measurements. In addition, the preference percentages do not show statistically significant differences between treatment means; and do not distinguish preference for either tank. The petitioner should provide additional information on 1) % a.i. and application rate are needed to verify test results and provide additional information on the Fresh Cab pouches used in the repellency tests; 2) time spent/average time for mice in either tank; 3) compare treatment means at a significance level; 4) report standard error of means; 5) analyze data for normality; and 6) design better experimental procedures are more clearly to show repellency.

Background Information and Study Summary

Fir Needle Oil, *Abies balsams*, is extracted from the needles and twigs of the Balsam Fir tree. Fir needle oil is often used to combat the symptoms of colds - including sore muscles and chest congestion. Fir balsam has a crisp, clean Christmas tree aroma that is

uplifting, warming and calming. Reported to be an anodyne, antiseptic, diaphoretic, diuretic, masticatory, and vulnerary, fir balsam is a folk remedy for bronchitis, burns, cancer, catarrh, cold, consumption, cough, dysentery, earache, gleet, gonorrhea, heart ailments, leucorrhea, paralysis, rheumatism, scurvy, sores, ulcers, urogenital ailments, warts, and wounds.

Canadian wilderness oil, the manufacturing use product, contains 10% of fir needle oil, the active product and 90% of the inert ingredients. The end use product Fresh Cab which contains 2.0% of fir needle oil, the active ingredient, is formulated with Canadian wilderness oil and [redacted]

Directions for Use (OPPTS 860.1200)

EARTH-KIND, Inc. DBA Crane Creek Gardens has submitted proposed labels for the registration of Canadian Wilderness Oil (MP) and Fresh Cab (EP).

Fresh Cab, the EP

The proposed label for fresh cab has described the general information, direction for use, precautionary statements, first aid, storage and disposal.

Indoors: Use in non-living areas (attics, basements. cellars, storage areas, garages, sheds. pantries and barns). Place one scent pouch pan 8 square feet in areas to be protected (i.e. use 4 pouches in a single car garage or one pouch in a pantry). Replace when scent has diminished. The product can last about 30 days indoors. Length of effectiveness depends or air exchange rates and temperature.

Enclosed Spaces: Use in tractors, trucks, electric junction boxes (see side panel for more uses). Place four scent pouches per storage unit per season to freshen the average size camper boat, truck or auto. Replace scent pouches when scent has diminished, Lasts up to 3 months in cold storage areas Length of effectiveness depends on air exchange rates and temperature condition of storage areas.

TABLE 1. Summary of End-Use Fir Needle Product Fresh Cab

Trade Name	Reg. No.	ai (% of formulation)	Formulation Type	Target uses in U.S.	Target Pests	Label Version
Fresh Cab	82016-R	2.0%	[redacted]	enclosed areas such as tractor cabs, electrical boxes, cabin cruisers, RV homes, and in non-living areas such attics, cellars, storage areas, garages, etc	Rodents	Draft; not dated.

Canadian wilderness oil, the MP

The proposed label for Canadian wilderness oil, the MP, has described information of first aid, precautionary statements, hazards to human and domestic animals, storage and disposal and environmental hazards.

Conclusions:

End-use product Fresh Cab

The submitted label for the end-use product (Fresh Cab, EPA Reg. No. 82016-R), a rodent repelling biopesticide, is not acceptable. The petitioner needs to submit a revised label with the standard of label format. The descriptions of environmental hazards to humans and domestic animals, personal protective equipment (PPE), and hotline number, etc. have been provided.

Canadian wilderness oil, MP

The submitted label for Canadian wilderness oil (EPA Reg. No. 82016-E), the manufacturing use product is not acceptable. The petitioner needs to submit a revised label with the standard of label format. The descriptions of directions for use, hotline number, hazards to humans and domestic animals, and personal protective equipment (PPE), etc have been provided in the label.

Acute Toxicity (OPPTS 870.1100 - 1300 & 870.2400 – 2600)

EARTH-KIND, Inc. DBA Crane Creek Gardens has submitted acute toxicity studies (MRIDs: 467844-02 through-07) using the technical product fir needle oil as test material for acute oral toxicity, acute dermal toxicity, acute inhalation toxicity and skin sensitization studies. The studies were conducted at Product Safety Laboratories, Dayton, NJ.

The manufacturing use product, Canadian wilderness oil, containing 10% of fir needle oil, the active ingredient and 90% of the inert ingredients was also tested for acute oral toxicity, acute dermal toxicity, acute inhalation toxicity and skin sensitization studies. The studies were conducted at Product Safety Laboratories, Dayton, NJ.

Acute oral toxicity study (OPPTS 870.1100)

Test animals: Each set of three female rats were weighed 167-201 g on the day of dosing for fir needle oil test and165-170 g on the day of dosing for Canadian wilderness oil. The young adult animals, 8-11 weeks old, were housed individually in suspended stainless steel cages with mesh floors. The animals were fed Purina Rodent Chow No. 5012. Filtered tap water was available *ad libitum*. The environmental conditions of the animal room were as follows: temperature, 19-24°C and photoperiod, 12 hour light/dark cycle. Relative humidity and air changes per hour were not reported.

Methods: Rats were ear-tagged: Nos. 4181, 4430, and 4431 and were acclimated for 6 or 22 days and fasted overnight prior to dosing for fir needle test; and rats were ear-tagged: Nos. 4513, 4536, and 4537 and were acclimated for 8 or 9 days and fasted overnight prior to dosing for Canadian wilderness oil test. The test material (5000 mg/kg body weight) was dosed by gavage. Body weight was recorded prior to dosing, and on days 7 and 14. The test animals were observed for mortality and clinical signs of toxicity during the first several hours post-dosing and at least daily for 14 days. All animals were necropsied.

Acute dermal toxicity study (OPPTS 870.1200)

Test animals: Each set of five male and five female Sprague-Dawley rats were assigned, and weighed 307-324 g (males) and 207-220 g (females) for fir needle oil test; and weighed 316-336 g (males) and 203-224 g (females) for Canadian wilderness oil test on the day of treatment. The young adult animals, 9-10 weeks old, were housed individually in suspended stainless steel cages with mesh floors. The animals were fed Purina Rodent Chow No. 5012 and filtered tap water was available *ad libitum*. The environmental conditions of the animal room were as follows: temperature, 19-22EC and photoperiod, 12 hour light/dark cycle. Relative humidity and air changes per hour were not reported.

Methods: Rats were ear-tagged: Male – Nos. 4493 to 4497; Female – Nos. 4498 to 4502 for fir needle oil test; and rats were ear-tagged: Male – Nos. 4756 to 4760; Female – Nos. 4761 to 4765 for Canadian wilderness oil test. The rats were acclimated for 15 days and 17 days, respectively. The test material (5000 mg/kg body weight) was applied evenly over a 2 x 3 inches (approximately 10% of the body surface) area of the dorsal trunk and covered with a gauze pad. The gauze pad and entire trunk were wrapped with Durapore tape. The coverings were removed after 24 hours and excess test material removed. The test animals were observed during the first several hours after treatment for mortality, signs of gross toxicity, and behavior changes and daily thereafter for 14 days. The rats were weighed prior to treatment and on days 7 and 14. The rats were euthanized on day 14 and necropsied.

Acute inhalation toxicity study (OPPTS 870.1300)

Test animals: Each set of five male and five female rats were assigned, and weighed 310-351 g (males) and 212-233 g (females) and weighed 320-332 g (males) and 212-244 g (females) for the test of Canadian wilderness oil on the day of treatment. The young adult animals, 9-10 weeks old, were housed individually in suspended stainless steel cages with mesh floors. The animals were fed Purina Rodent Chow No. 5012. Tap water was available *ad libitum*. The environmental conditions of the animal room were as follows: temperature, 19-22EC and photoperiod, 12 hour light/dark cycle. Relative humidity and air changes per hour were not reported.

Methods: Rats were ear-tagged: Male – Nos. 4706 to 4710 and female – Nos. 4711 to 4715 for the test of fir needle oil; and male – Nos. 4716 to 4720 and female – Nos. 4721 to 4725 for the test of Canadian wilderness oil. The rats were acclimated for 15 days and 16 days, respectively, prior to exposure. The animals were exposed to the concentration shown in Table 1. The rats were exposed nose-only in a Mini Nose-Only inhalation chamber for four hours and 1 minute. They were observed during exposure, upon removal from the chamber, and at least once daily thereafter for 14 days. They were weighed prior to test material exposure and on days 7 and 14. All surviving rats were sacrificed and necropsied on day 14.

Acute eye irritation study (OPPTS 870.2400)

Test Animals: One set of young adult New Zealand White rabbits (one male and two female) for fir needle oil test and three female young adult New Zealand White rabbits for Canadian wilderness oil test were housed individually in suspended stainless steel cages with mesh floors. The animals were fed Pelleted Purina Rabbit Chow No. 5326. Filtered tap water was available *ad libitum*. The environmental conditions of the animal room were as follows: temperature, 19-21EC and photoperiod, 12 hour light/dark cycle. Relative humidity and air changes per hour were not reported.

Methods: Rabbits were ear-tagged: Nos. 15004 (male) and 15003 and 15005 (females) for fir needle oil test; and Nos. 15053 (male) and 15051 and 15052 (females) for Canadian wilderness oil test. The rabbits were acclimated for 6 days and 7 days, respectively. The fur on the dorsal trunk of each rabbit was clipped on the day prior to treatment. The rabbits were treated with 0.5 mL of test material applied on a 6 cm^2 clipped intact site, and the site covered with gauze pad. The pad and entire trunk were wrapped with semi-occlusive Micropore tape. Elizabethan collars were placed on the rabbits. The covering and the collar were removed 4 hours later and the site cleansed to remove any residual test material. The animals were observed at least once daily for gross toxicity and behavior changes during the study. Dermal examination was recorded at 1, 24, 48, and 72 hours and at 7, 10, and 14 days after removal of the patch.

Acute skin irritation study (OPPTS 870.2500)

Test animals: Each set of young adult New Zealand White rabbits (one male and two female) were housed individually in suspended stainless steel cages with mesh floors for the tests of fir needle oil and Canadian wilderness oil. The animals were fed Pelleted Purina Chow No. 5326. Filtered tap water was available *ad libitum*. The environmental conditions of the animal room were as follows: temperature, 19-22EC and photoperiod, 12 hour light/dark cycle. Relative humidity and air changes per hour were not reported.

Methods: Rabbits were ear-tagged: Nos. 15004 (male) and 15003 and 15005 (females). The rabbits were acclimated for 6 days. The fur on the dorsal trunk of each rabbit was clipped on the day prior to treatment. The rabbits were treated with 0.5 mL of test material applied on a 6 cm^2 clipped intact site, and the site covered with gauze pad. The pad and entire trunk were wrapped with semi-occlusive Micropore tape. Elizabethan collars were placed on the rabbits. The covering and the collar were removed 4 hours

later and the site cleansed to remove any residual test material. The animals were observed at least once daily for gross toxicity and behavior changes during the study. Dermal examination was recorded at 1, 24, 48, and 72 hours and at 7, 10, and 14 days after removal of the patch.

Skin sensitization study (OPPTS 870.2600)

Test animals: Each set of thirty-four male Hartley guinea pigs weighed 310-367 g for fir needle oil test; and weighed 309-446 g for Canadian wilderness oil test. The young adult animals were housed individually in suspended stainless steel cages with mesh or plastic perforated floors. The animals were fed pelleted Purina Guinea Pig Chow No. 5025. Filtered tap water was available *ad libitum*. The environmental conditions of the animal room were as follows: temperature, 19-23EC and photoperiod, 12 hour light/dark cycle. Relative humidity and air changes per hour were not reported.

Methods: For fir needle oil test, male guinea pigs were marked with color codes and grouped: Preliminary irritation testing – Nos. 27493 to 27496; Test – Nos. 27702 to 27721; Naive Control – Nos. 27722 to 27731. The guinea pigs were acclimated for 5-10 days. For Canadian wilderness oil test, male guinea pigs were marked with color codes and grouped: Preliminary irritation testing – Nos. 27497 to 27500; Test – Nos. 27732 to 27751; Naive Control – Nos. 27752 to 27761. The guinea pigs were acclimated for 10-12 days. The animals were induced and challenged according to the method of Buehler. The dorsal and flank areas of 20 test guinea pigs and 10 naive control animals were clipped prior to each treatment. For the induction, 0.4 mL undiluted test material was applied to the animal using a Hill Top Chamber secured with non-allergenic adhesive tape. The chamber was removed after six hours and excess test material removed. The procedure was repeated once each week for three consecutive weeks. Twenty-seven days after the first induction, the test animals were challenged with 0.4 mL of 50% w/w test material in mineral oil under occlusion to naive sites. At challenge, a naive control group (10 animals) was treated with 0.4 mL of 50% w/w test material in mineral oil. Reactions were scored at approximately 24 and 48 hours following induction and challenge application.

The results for acute studies from the submitted studies and literature reports are summarized in Table 3.

TABLE 3 Acute Toxicity Profile - Test Substance

Guideline No.	Study Type	MRID(s)	Results	Toxicity Category
870.1100	Acute oral [rat]	46784402	LD_{50} = >5000 mg/kg (Fir needle oil)	IV
		46784408	LD_{50} = >5000 mg/kg (Canadian wilderness oil, contains 10% of fir needle oil)	IV
870.1200	Acute dermal [rat]	46784403	LD_{50} = >5000 mg/kg (Fir needle oil)	IV

		46784409	LD_{50} = >5000 mg/kg (Canadian wilderness oil, contains 10% of fir needle oil)	IV
870.1300	Acute inhalation [rat]	46784404	LD_{50} = >2.09 L (Fir needle oil)	IV
		46784410	LD_{50} = >2.07 L (Canadian wilderness oil, contains 10% of fir needle oil)	IV
870.2400	Acute eye irritation [rabbit]	46784405	The maximum average score was 17.7 at one hour after test material instillation. Fir Needle, Canadian was mildly irritating.	III
		46784411	The maximum average score was 15.7 at one hour after test material instillation. Canadian Wilderness Oil was mildly irritating.	III
870.2500	Acute dermal irritation [rabbit]	46784406	The primary irritation index was 5.1. Fir Needle, Canadian was severely irritating.	II
		46784412	The primary irritation index was 1.4. Canadian Wilderness Oil was slightly irritating.	IV
870.2600	Skin sensitization [guinea pig]	46784407	Several test animals showed positive signs of reactivity at 24 and 48 hours, respectively, after challenge. Fir Needle, Canadian was a dermal sensitizer.	A dermal sensitizer
		46784413	After three consecutive weekly inductions, no test animals showed any positive signs of reactivity at 24 and 48 hours after challenge. Canadian Wilderness Oil was **not** a dermal sensitizer.	**not** a dermal sensitizer

Conclusions:

The packet classification is **ACCEPTABLE** for the acute oral toxicity study with rats under OPPTS guideline 870.1100 for fir needle oil and Canadian wilderness oil. The oral LD_{50} for female rats was greater than 5000 mg/kg for both products. This places fir needle oil and Canadian wilderness oil in TOXICITY CATEGORY IV.

The packet classification is **ACCEPTABLE** for the acute dermal toxicity study with rats under OPPTS guideline 870.1200. The dermal LD_{50} for males, females, and combined was greater than 5000 mg/kg for fir needle oil and Canadian wilderness oil. This places fir needle oil and Canadian wilderness oil in TOXICITY CATEGORY IV.

The packet classification is **ACCEPTABLE** for the acute inhalation toxicity study with rats under OPPTS guideline 870.1300 for fir needle oil and Canadian wilderness oil. The inhalation LC_{50} for males, females, and combined was > 2.07 mg/L and >2.09 mg/L, respectively. This places fir needle oil and Canadian wilderness oil in TOXICITY CATEGORY IV.

The packet classification is **ACCEPTABLE** for the acute eye irritation study with rats under OPPTS guideline 870.2400 for fir needle oil and Canadian wilderness oil. The maximum average score was 17.7 and 15.7 at one hour after test material instillation. Fir Needle oil and Canadian wilderness oil were mildly irritating. This places fir needle oil and Canadian wilderness oil in TOXICITY CATEGORY III.

The packet classification is **ACCEPTABLE** for the acute dermal irritation study with rats under OPPTS guideline 870.2400 for fir needle oil and Canadian wilderness oil. Fir Needle, Canadian was severely irritating. The primary irritation index for fir needle oil was 5.1. This places fir needle oil in TOXICITY CATEGORY II. Canadian Wilderness Oil was slightly irritating. The primary irritation index was 1.4. This places Canadian wilderness oil in TOXICITY CATEGORY IV.

The packet classification for fir needle oil and Canadian wilderness oil is **ACCEPTABLE** for the acute skin sensitization study with pigs under OPPTS guideline 870.2600. Several test animals showed positive signs of reactivity at 24 and 48 hours, respectively, after challenge. Fir Needle, Canadian was a dermal sensitizer. After three consecutive weekly inductions, no test animals showed any positive signs of reactivity at 24 and 48 hours after challenge. Canadian Wilderness Oil was **not** a dermal sensitizer.

Inert ingredient information may be entitled to confidential treatment

Waiver Request

The petitioner has submitted a waiver request (MRID 784415) for acute oral toxicity, acute dermal toxicity, acute inhalation toxicity, primary eye irritation, primary dermal irritation, and dermal sensitization studies for Fresh Cab.

Fresh Cab (EPA Reg. No. 82016-R) is an end-use product (EP) used to repel rodents. The active ingredient is 2.0% w/w Balsam Fir Oil and the TGAI/MP in the EP is 20% w/w Canadian Wilderness Oil (EPA Reg. No. 82016-E, a simultaneous submission for registration – Task 06-063; containing 10% Balsam Fir Oil). [redacted]

The registrant presented the rationale for waivers: 1) low acute toxicity of the active ingredient Canadian Wilderness Oil (Toxicity category IV for acute oral, dermal, inhalation, and skin irritation; Toxicity category III for eye irritation; and not a dermal sensitizer; MRIDs 46784408 to 46784413), 2) no toxicity of the inert [redacted] - an EPA cleared inert and on inert list 4A.

BPPD concludes that the submitted information in support of the requested waivers for acute oral toxicity, acute dermal toxicity, acute inhalation toxicity, primary eye irritation, primary dermal irritation, and dermal sensitization studies for Fresh Cab is acceptable.

Product Properties (OPPTS 830 Series GLNs)

Inert ingredient information may be entitled to confidential treatment

End Use Product, Fresh Cab

EARTH-KIND, Inc. DBA Crane Creek Gardens has submitted a petition for the registration of Fresh Cab, containing fir needle oil (the active ingredient) of 2%. Fresh Cab is the end use product. In support of this petition, the petitioner has submitted product chemistry studies of the end use product, Fresh Cab at nominal concentration of 2.0% of the active ingredient, fir needle oil (MRIDs 46784401 and 46784414), and basic Confidential Statements of Formula (CSFs), dated 12/10/2005 (Table 4).

TABLE 4. Nominal CSF concentrations and limits for Fresh Cab[a]

Ingredients (CAS number)	PC Code	Purpose	Concentration (% by weight)		
			Nominal	Lower	Upper
Active Ingredient					
Canadian Wilderness Oil containing 10% Balsam Fir Oil[b]		Active	20% 2.0%, a.i.	1.9%, a.i.	2.1%, a.i.
Inert ingredient					
[redacted]					

[a] Data from MRID 46784414.
[b] The MSDS lists CAS No. 8021-28-1 and the bean sheet lists PC code 129035 for Fir needle oil.

Physical and Chemical Characteristics

The product chemistry data base for Fresh cab is essentially complete. There are no reported impurities of toxicological concern. The Series 830 physical and chemical properties are given in Table 5.

Oxidation/reduction and explodability are not addressed but not applicable. A waiver was requested for corrosion characteristics.

TABLE 5. Physical and Chemical Properties for Fresh Cab[a]			
Guideline Reference No.	**Property**	**Description of Result**	**Methods**
830.6302	Color	Tan	
830.6303	Physical State	Granular solid	
830.6304	Odor	Fresh woodsy scent	
830.6313	Stability	Not required for EP	
830.6314	Oxidation/Reduction: Chemical Incompatibility	**To be conducted**	
830.6315	Flammability	Not applicable, product is a solid, not a liquid.	
830.6316	Explodability	**To be conducted**	
830.6317	Storage Stability	The Agency waived this data requirement on May 11, 2005.	
830.6319	Miscibility	Not applicable, product is not intended for dilution with petroleum solvents.	
830.6320	Corrosion Characteristics	The registrant is requesting a waiver. The product is composed of non-corrosive formulation ingredients. The packaging materials and cardboard boxes are not corrosive.	
830.6321	Dielectric Breakdown Voltage	Not applicable, product is not a liquid and is not intended for use around electrical equipment.	
830.7000	pH	Not applicable, product is not intended for dilution with water.	
830.7050	UV/Visible	Not required for EP	
830.7100	Viscosity	No applicable, product is a solid.	
830.7200	Melting Range	Not required for EP	
830.7220	Boiling Range	Not required for EP	
830.7300	Bulk Density	43 lb/ft^3	CSF
830.7370	Dissociation Constant in Water	Not required for EP	
830.7550	Partition Coefficient	Not required for EP	
830.7840	Water Solubility	Not required for EP	
830.7950	Vapor Pressure	Not required for EP	

[a] Data from MRID 46784414.

Canadian Wilderness Oil

EARTH-KIND, Inc. DBA Crane Creek Gardens has submitted a petition for the registration of Canadian Wilderness Oil containing fir needle oil (the active ingredient) of 10%. Canadian Wilderness Oil is the manufacturing use product. In support of this petition, the petitioner has submitted product chemistry studies of the manufacturing use product, Canadian Wilderness Oil at nominal concentration of 10.0% of the active ingredient, fir needle oil (MRID 46784401), and basic Confidential Statements of Formula (CSFs), dated 12/10/2005 (Tables 6a & 6b).

TABLE 6a. Nominal CSF concentrations and certified limits for Canadian Wilderness Oil (basic formulation)[a]					
Ingredients (CAS number)	**PC Code**	**Purpose**	**Concentration (% by weight)**		
			Nominal	**Lower**	**Upper**
Active Ingredient					
Fir needle oil (CAS No. 8021-28-1)	129035	Active ingredient	10.0	9.5	10.5
Inert Ingredients[b]					
[redacted]					

Inert ingredient information may be entitled to confidential treatment

TABLE 6a. Nominal CSF concentrations and certified limits for Canadian Wilderness Oil (basic formulation)[a]					
Ingredients (CAS number)	PC Code	Purpose	Concentration (% by weight)		
			Nominal	Lower	Upper
[redacted]					

[a]Data from CSF
[b]Purpose in formulation not specified on CSF
[c]CAS No. incorrect on CSF
[d]Name incorrect on CSF

Inert ingredient information may be entitled to confidential treatment

TABLE 6b. Nominal CSF concentrations and certified limits for Canadian Wilderness Oil (alternate formulation)[a]					
Ingredients (CAS number)	**PC Code**	**Purpose**	**Concentration (% by weight)**		
			Nominal	**Lower**	**Upper**
Active Ingredient					
Fir needle oil (CAS No. 8021-28-1)	129035	Active ingredient	10.0	9.5	10.5
Inert Ingredients[b]					
[redacted]					

Inert ingredient information may be entitled to confidential treatment

TABLE 6b. Nominal CSF concentrations and certified limits for Canadian Wilderness Oil (alternate formulation)[a]					
Ingredients (CAS number)	PC Code	Purpose	Concentration (% by weight)		
			Nominal	Lower	Upper
[redacted]					

[a]Data from CSF
[b]Purpose in formulation not specified on CSF
[c]CAS No. incorrect on CSF
[d]Name is incorrect on CSF

Inert ingredient information may be entitled to confidential treatment

Physical and Chemical Characteristics

The product chemistry data base for Canadian wilderness oil is essentially complete. There are no reported impurities of toxicological concern. The Series 830 physical and chemical properties are given in Table 7. Oxidation/reduction and explodability are not addressed but not applicable. A waiver was requested for corrosion characteristics.

TABLE 7. Physical and Chemical Properties for Canadian Wilderness Oil[a]			
Guideline Reference No./Property		**Description of Result**	**Methods**
830.6302	Color	Pale yellow to amber	
830.6303	Physical State	Liquid	
830.6304	Odor	Fresh woodsy scent	
830.6313	Stability	Not required for MP	
830.6314	Oxidation/Reduction: Chemical Incompatibility	**To be conducted**	
830.6315	Flammability	Flash point = 73°C	Closed cup
830.6316	Explodability	**To be conducted**	
830.6317	Storage Stability	**To be conducted**	
830.6319	Miscibility	N/A, product not intended for dilution with petroleum solvents	
830.6320	Corrosion Characteristics	**To be conducted**	
830.6321	Dielectric Breakdown Voltage	Not required for MP	
830.7000	pH	5	
830.7050	UV/Visible Absorption	Not required for MP	
830.7100	Viscosity	46.943 ± 0.307 cS @ 20°C 16.940 ± 0.029 cS @ 40°C	ASTM D445/D446
830.7200	Melting Range	Not required for MP	
830.7220	Boiling Range	238 to 410°F @ 10 torr absolute pressure	Not provided
830.7300	Density/Relative Density/Bulk Density	0.981 to 0.998 g/mL @ 25°C	Not provided
830.7370	Dissociation Constant in Water	Not required for MP	
830.7520	Particle Size/Distribution	N/A, product is a liquid	
830.7550	Partition Coefficient	Not required for MP	
830.7840	Water Solubility	Not required for MP	
830.7950	Vapor Pressure	Not required for MP	

[a]Data from pp. 6-8, MRID 46784401

Conclusions:

End Use Product, Fresh Cab

The submitted product chemistry study for Fresh Cab is not adequate to satisfy the OPPTS guidelines 830 Series. The registrant needs to 1) consistently list the percentage of the a.i. on the CSF (2.0%) and label (2%); 2) provide a MSDS of the TGAI/MP Canadian wilderness Oil from the supplier listed on the CSF and remove any others; and 3) provide the methods for physical/chemical properties; 4) data are provided for oxidation/reduction (chemical incompatibility and explodability). The certified limits of

the ingredients are within the recommended range in guideline OPPTS 830.1750. An analytical method for Fresh Cab was waived by the Agency on May 11, 2005.

The waiver request for corrosion characteristics study is acceptable. The petitioner claimed that product is composed of non-corrosive formulation ingredients. The packaging materials and cardboard boxes are not corrosive.

Canadian Wilderness Oil, MP

The submitted product chemistry study for Canadian wilderness oil is unacceptable. Since no TGAI data have been submitted with this petition, product chemistry data requirements of combined TGIA/MP must be followed for Canadian wilderness oil, the MP. The classification of the product chemistry study can be upgradeable if 1) the CAS No. for [redacted] is corrected on the CSFs; 2) the names for [redacted] are corrected on the CSFs; 3) the purposes of the inert ingredients in the formulations and their suppliers are specified on the CSFs; 4) MSDSs for the inert ingredients are provided by the suppliers listed in MRID 46784401; 5) descriptions of the process conditions and equipment and product packaging are submitted; 6) methods are provided for the relevant physical and chemical characteristics; 7) data are provided for chemical incompatibility, explodability, storage stability and corrosion characteristics; and 8) PC codes are needed to be assigned for [redacted]

The petitioner must submit product chemistry study for fir needle oil (TGAI) based on OPPTS Guidelines 830 Series to meet product chemistry data requirement for the Section 3 registration as specified under 40CFR 158.690(a).

Product Performance (OPPTS 810.1000)

EARTH-KIND, Inc. DBA Crane Creek Gardens has submitted a product performance study for the end use product, fresh cab (MRID 467844-16). Fresh Cab contains 2.0% of the active ingredient, fir needle oil.

Fresh Cab Pouches - Various herbal ingredients in biodegradable pouches formulated by Crane Creek Gardens were used for this study. No details were provided for the pouches or herbal ingredients, % a.i., application rate, etc.. The study was conducted in two phases. Phase I used five wild house mice/testing tank for 14 days in an effort to have a large sample size. However, a behavioral hierarchy was encountered which appeared to confound the data as juvenile mice were attacked by larger and older mice. Phase II was initiated with only a single mouse/tank pair for 17 days.

Seventy- two live mice were trapped on nearby farms in Wellington, Colorado using Sherman live traps. The mice were transported to the test facility, removed from the traps and randomly placed in one of four stock tanks not to exceed 20 mice per tank. The ages and size of the mice varied. The stock tanks were 100 gallon livestock tanks with a floor area of ~6,600 cm^2. Tap water and Purina 5001 rodent diet were supplied *ad*

libitum through out the testing in each tank. PVC shelters and pieces of plywood were added to each tank and wood shavings (bedding) was placed on the floor of the tanks and changed once each week.

To aid in restricting odor throughout the study rooms, tank lids were constructed of lumber and hardware cloth to keep mice from escaping. Further, the lids were wrapped several times with plastic to retain the odor in the treatment tank and aid in restricting the odor from entering the control tank. Lids were sealed on the tanks with foam weather-stripping. Two tanks were connected with a 1.5 inch diameter hardware cloth tube in the shape of an inverted U with the arms approximately 2 inches from the tank floor. The mice quickly used this pathway and were observed frequenting the area during the day.

On day 0 of the exposure period, the mice were randomly placed into the tank pairs. Likewise, two Fresh Cab pouches were placed into one of the two tanks of each tank pair. The other tank remained as the control. On day 0, Purina 5001 rodent diet was weighed and presented in a single cup per tank. Diet consumption was measured each day to the nearest 0.1g and accounted for spilled food and food that was in the bedding.

Environmental monitoring was performed daily during the test period. Temperature and humidity were monitored in each room and a light cycle of 12 hours light: 12 hours dark was maintained.

All mice were observed once daily during the holding and exposure periods as a measure of health. For Phase I, there were five mice in each tank and for Phase II there was one mouse in each tank. Repellency to Fresh Cab was noted as the position of the mice in the tanks.

Results of Repellency to Fresh Cab

Phase I indicated a 38.8% preference for the treatment tank or 61.2% repellency from the treatment tank containing the Fresh Cab pouches. In Phase II, the repellency increased to 76% due to the response of a single mouse in the 17-day exposure period. Average repellency during the two phases was 68.6%. The lower observed repellency in Phase I was attributed to behavior hierarchy of the mice since dead and barbered juvenile mice were observed in the tanks. Thus, Phase II was redesigned to monitor a single mouse at a time in the tanks.

Conclusions:

Based on the test results, it can not be concluded that mice are being repelled by this product. The means for control treatment tanks must be reported with their associated standard errors. The data must be statistically analyzed for mean comparison of two treatment means and determination of statistically significant differences between the two groups (treated and untreated/control).